IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MEIJER, INC. and MEIJER DISTRIBUTION, INC., on behalf of themselves and all others similarly situated,	**Civil Action No.**
Plaintiffs,	**CLASS ACTION COMPLAINT**
v.	
ABBOTT LABORATORIES; FOURNIER INDUSTRIE ET SANTE; AND LABORATORIES FOURNIER S.A.,	**JURY TRIAL DEMANDED**
Defendants.	

Plaintiffs, on behalf of themselves and the class defined below, bring this antitrust action against Abbott Laboratories ("Abbott,") Fournier Industrie Et Sante, and Laboratories Fournier S.A. ("Fournier," collectively "Defendants") and allege as follows based upon personal knowledge as to matters relating to themselves and upon the investigation of their counsel and information and belief as to all other matters:

NATURE OF THE CASE

1. This case arises from Defendants' unlawful scheme to maintain illegally a monopoly in the United States market for the cholesterol-lowering medicine sold under the brand name TriCor ("TriCor") and its AB-rated generic equivalents. Fenofibrate is the generic name for TriCor.

2. As alleged in greater detail herein, Defendants engaged in an unlawful anticompetitive scheme to prevent generic manufacturers from entering the market for TriCor and its generic equivalents in order to prevent competition and maintain their monopoly. Defendants' overall scheme to monopolize the market for TriCor and its generic equivalents involved several interrelated steps designed to work together to exclude generic competition.

Defendants filed a series of sham litigations against generic competitors, manipulated the pharmaceutical regulatory structure, and deliberately destroyed markets for competing generic versions of TriCor, all with goal of "evergreening" their TriCor monopoly.

3. Defendants implemented their scheme by repeatedly using the same basic strategy of altering their TriCor formulation and then destroying the market for the previously approved formulation, while delaying generic entry under the old formulation through sham litigations and manipulation of the thirty-month stay provision of the Hatch Waxman Act. The scheme worked in the following way: first, when a generic company sought to market a generic version of TriCor, Defendants altered their TriCor formulation in a medically insignificant way, but in a way that required approval by the United States Food and Drug Administration ("FDA") as a "new drug." Second, Defendants obtained FDA approval to market the "new" TriCor formulation, thereby requiring any entity seeking to market a generic version of the "new" formulation to likewise obtain FDA approval. Third, Defendants aggressively switched patients over to the "new" formulation while taking affirmative steps to destroy the market for the old formulation, including removing the applicable code from the National Drug Data File ("NDDF"). Fourth, Defendants filed sham patent infringement litigation against the generics, triggering the automatic thirty-month Hatch Waxman stay, to delay generic entry under the old formulation while Defendants converted patients to the "new" formulation and destroyed the market for the old formulation. After the thirty-month stay expires and the generics are prepared to come to market with the "old" formulation, Defendants had effectively destroyed the market for the old formulation, and the generic companies desiring to market generic TriCor must apply to the FDA to market the "new" formulation. At this point, Defendants simply repeat the same steps, again altering their TriCor formulation.

4. As a result of Defendants' scheme, a generic drug company seeking to market generic TriCor becomes like the mythical Tantalus, having the market disappear each time it is approved to market a fenofibrate product. Defendants, on the other hand, are able to maintain indefinitely their monopoly on TriCor and its generic equivalents, generating supracompetitive profits in perpetuity.

5. Defendants have powerful, albeit improper, motives for their conduct. In the past year alone, Defendants had total sales of TriCor in excess of $750 million. Defendants know they would lose substantial sales to generic rivals if they had to compete with generic TriCor. Defendants also know that they cannot maintain their monopoly position against generic competition simply by bringing new formulations of TriCor to market. If Defendants launched and promoted their new formulations without also acting affirmatively to destroy the market for the old formulations, while simultaneously filing sham patent litigation against the companies seeking to market the old formulation, many patients and doctors would choose to use the lower-cost, generic old-formulation products. Thus, the only way Defendants can continue to charge supracompetitive prices for their products, without losing sales to lower-cost competitors, is for them to exclude the lower-cost competitors from the market.

6. As a result of their unlawful acts, Defendants have: (1) unreasonably restrained, suppressed, and eliminated competition in the market for TriCor and its generic equivalents; and (2) illegally maintained their monopoly in the market for TriCor and its generic equivalents.

7. Absent Defendants' unlawful conduct, less expensive generic versions of TriCor would have been on the market much earlier. Through its unlawful conduct, Defendants illegally deprived Plaintiffs (and the other direct purchasers who comprise the class alleged

herein) of access to substantially lower-priced generic versions of TriCor, thereby causing Plaintiffs and the Class to overpay for TriCor by hundreds of millions of dollars.

JURISDICTION AND VENUE

8. This Court has jurisdiction over the subject matter of this civil action pursuant to 28 U.S.C. §§ 1331 and 1337.

9. Venue is proper in this Court under 28 U.S.C. § 1391 and 15 U.S.C. § 22 because: (1) Defendants transacts business, committed an illegal or tortious act, and/or is found within this district; and (2) a substantial portion of the affected trade and commerce described below has been carried out in this district.

PARTIES

10. Plaintiffs Meijer, Inc. and Meijer Distribution, Inc. (collectively "Meijer") are corporations organized under the laws of the State of Michigan, with their principal places of business in Grand Rapids, Michigan. Meijer is the assignee of the claims of the Frank W. Kerr Co., which, during the Class Period, as defined below, purchased TriCor directly from one or more Defendants.

11. Defendant Abbott is a corporation organized under the laws of the State of Illinois, with its principal place of business in Abbott Park, Illinois. Abbott develops, manufactures, and markets pharmaceutical and related products in the United States.

12. Defendants Fournier Industrie et Sante and Laboratories and Fournier, S.A. are French corporations having their principal place of business at 42 Rue de Longvie, 21300 Chenove, France. Abbott is the licensee from Fournier of the four patents Defendants asserted against companies seeking to manufacture generic TriCor.

INTERSTATE TRADE AND COMMERCE

13. During all or part of the Class Period, one or more Defendants manufactured and sold substantial amounts of TriCor in a continuous and uninterrupted flow of commerce across state and national lines and throughout the United States.

14. At all material times, TriCor manufactured and sold by one or more Defendants was shipped across state lines and sold to customers located outside its state of manufacture.

15. During all or part of the Class Period (defined below), Defendants transmitted funds as well as contracts, invoices and other forms of business communications and transactions in a continuous and uninterrupted flow of commerce across state and national lines in connection with the sale of TriCor.

16. In furtherance of its efforts to monopolize and/or restrain competition in the market for TriCor and its generic equivalents, Defendants employed the United States mails and interstate and international telephone lines, as well as means of interstate and international travel.

17. Defendants' efforts to monopolize and restrain competition in the market for TriCor and its generic equivalents alleged herein has substantially affected interstate and foreign commerce.

CLASS

18. Plaintiffs brings this action on behalf of itself and the following class:

> All persons and entities in the United States who purchased TriCor directly from Defendants at any time from April 9, 2002 through the present (the "Class Period"). Excluded from the class are defendants, their parents, employees, subsidiaries and affiliates, and federal and state government entities (the "Class").

19. The Class is so numerous that joinder of all members is impracticable. Plaintiffs believe that the Class numbers one hundred or more.

20. There are questions of law or fact common to the Class, including:

a. whether Defendants maintained monopoly power in delaying generic entry;

b. whether Defendants' litigation asserting infringement of its patents described herein was baseless;

c. whether Defendants' actions illegally maintained its monopoly power;

d. whether Defendants' conduct caused antitrust injury to the business or property of its direct purchaser customers.

21. These and other questions of law and fact are common to the members of Class and predominate over any questions affecting only individual members.

22. Plaintiffs' claims are typical of the claims of the Class because all Class members, including Plaintiffs, sustained antitrust injury in the same way as a result of Defendants' wrongdoing, and the claims of each Class member arise out of the same nucleus of operative facts and are based on the same legal theories.

23. Plaintiffs will fairly and adequately represent and protect the interests of the Class. Plaintiffs have retained counsel who are experienced in class action and antitrust litigation, and plaintiffs have no interest in this litigation that is adverse to, or in conflict with, the interests of the other members of the Class.

24. A class action is superior to the other available methods for the fair and efficient adjudication of this controversy. Plaintiffs know of no difficulty that will be encountered in the management of the claims advanced by the Class that would preclude class certification.

FACTUAL ALLEGATIONS

A. The Regulatory Structure For Brand And Generic Drugs

25. The manufacture and commercial sale of pharmaceutical drugs are regulated by the FDA pursuant to the Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301 et seq. (1994) (the "FD&C Act"). Under the FD&C Act, approval by the FDA, the governmental body charged with the regulation of the pharmaceutical industry, is required before a company may begin selling a new drug in interstate commerce in the United States. 21 U.S.C. § 355(a). Premarket approval for a new drug must be sought by filing a new drug application ("NDA") with the FDA under § 355(b) of the FD&C Act demonstrating that the drug is safe and effective for its intended use.

26. Congress passed the "Hatch-Waxman Amendments" to the FD&C Act in 1984 after concluding, among other things, that the FD&C Act's drug-approval process delayed the entry of relatively inexpensive generic drugs into the marketplace. The Hatch-Waxman Amendments permit generic-drug manufacturers to file an Abbreviated New Drug Application ("ANDA") that expedites the drug-approval process, principally because the ANDA may incorporate data that an earlier manufacturer already submitted to the FDA regarding the earlier drug's safety and efficacy in a New Drug Application ("NDA").

27. New drugs that are approved for sale in the United States by the FDA are typically covered by patents, which provide the patent owner with the right to seek to exclude others from making, using and/or selling (depending on the scope of the patent) that new drug in the United States for the duration of the patents, plus any extension of the original patent period ("FDA Exclusivity Period") granted pursuant to the Hatch-Waxman Amendments.

28. Pursuant to 21 U.S.C. § 355(b), in its NDA the pioneer drug manufacturer must list all patents that claim the drug for which FDA approval is being sought, or that claim a

method of using the drug, and with respect to which a claim of patent infringement could reasonably be asserted against an unlicensed manufacturer or seller of the drug. Once the NDA is approved by the FDA, any claimed patents must be listed with the NDA in a publication known as the Approved Drug Products With Therapeutic Equivalence Evaluations. This publication is commonly referred to as the "Orange Book."

29. Federal regulations impose strict limitations on the types of patents that an NDA holder can submit to the FDA for listing in the Orange Book. *See generally* 21 C.F.R. § 314.53. One such limitation is imposed by 21 C.F.R. § 314.53(b), which explicitly prohibits NDA holders from listing any patent in the Orange Book unless a claim of infringement could reasonably be asserted on the basis of such a patent.

30. Despite the FDA regulations that limit the types of patents that NDA holders can list in the Orange Book, it has become common for brand companies to list any and every patent they can obtain in the Orange Book so as to force generic manufacturers to file what, as described below, is commonly known as a Paragraph IV certification, and the FDA does not police this practice. The FDA employs no adjudicatory or other process to determine whether a patent submitted by an NDA holder qualifies for listing under the applicable regulations.

31. Generic drugs are drugs that the FDA has found to be bioequivalent to their corresponding brand name drugs. A generic drug provides identical therapeutic benefits and has the exact same side effects and safety profile as its corresponding brand name drug. Generic drugs invariably cost substantially less than the branded drugs to which they are bioequivalent. Typically, the first generic version of a brand name drug is sold at a substantial discount to the brand, followed by increasingly steeper discounts as more generics enter the market. Under the Hatch-Waxman Amendments, a generic drug manufacturer may seek expedited FDA approval to market a generic version of a brand name drug with an approved NDA by filing an ANDA

pursuant to 21 U.S.C. § 355(j). An ANDA relies on the safety and efficacy data already filed with the FDA by the manufacturer of the equivalent brand name drug.

32. The ANDA applicant is required to certify in one of four ways with respect to any purported patent that is listed in the Orange Book as covering an NDA drug. If an ANDA applicant seeks approval to market a drug before the expiration of one or more patents listed in the Orange Book that purportedly apply to that drug, it must make a certification for each such patent, according to 21 U.S.C. § 355(j)(2XA)(vii)(IV), "that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted." Such a certification is known as a "Paragraph IV certification."

33. The filing of a Paragraph IV certification permits the holder of any patent identified in the Orange Book as applying to the listed drug to assert a cause of action for patent infringement against the ANDA applicant. If such an action is brought within 45 days from receipt of notification of any Paragraph IV certification, the FDA cannot grant final approval of the ANDA until the earlier of 30 months from the patent holder's receipt of notification of the Paragraph IV certification, the date on which the court that is hearing the patent infringement case holds that such patent is invalid, not infringed, or unenforceable, or the date on which the case is withdrawn, discontinued, dismissed, or otherwise terminated by the patent holder (the "stay period").

34. The mere filing of an infringement action in response to a Paragraph IV certification, regardless of the action's underlying merit, gives the brand-name company the functional equivalent of a self-effectuating preliminary injunction blocking the entry of a generic competitor, without the brand company ever having to establish likelihood of success on the merits, irreparable harm, balance of hardships or the public good. Indeed, as a practical matter the brand name company *wins the lawsuit simply by filing it*, as it automatically protects its

monopoly for up to two and a half years while the infringement action grinds through the court system. This creates a strong incentive to file suit against the ANDA filers because there are no disgorgement provisions for profits earned during the thirty-month period of exclusivity if a court eventually determines that the suit was without merit.

35. An improper Orange Book listing also has additional anti-competitive effects because the first generic company to file an ANDA with a Paragraph IV Certification is, upon FDA approval, granted a 180-day period of exclusivity in relation to other generic manufacturers. 21 U.S.C. § 355(j)(5)(B)(iv). This 180 day exclusivity against other generic competitors is awarded to the first Paragraph IV filer regardless of whether or not the brand company institutes pre-approval patent infringement litigation in response to the Paragraph IV certification. Absent an improper Orange Book listing, no Paragraph IV certification would be required and, thus, no generic company would receive 180-day exclusivity.

36. If the holder of the listed patent does not file an infringement action within 45 days from receipt of the Paragraph IV notification, the FDA may grant final approval of the ANDA as soon as the FDA's other regulatory requirements are satisfied. If an ANDA has satisfied all FDA regulatory requirements, including those relating to bioequivalence to the drug covered by the subject NDA, and the stay period has not expired, the FDA will grant tentative approval of the ANDA. The FDA's grant of a tentative approval means that the FDA would have granted a final approval in the absence of the stay period that prevents the FDA from doing so. The ANDA applicant can sell the generic product in the United States only upon receipt of final approval from the FDA, not upon receipt of tentative approval.

37. Upon the ANDA applicant's receipt of tentative approval from the FDA, the stay period that follows the institution of a patent infringement suit in response to the Paragraph IV certification becomes a statutory barrier to market entry by the ANDA

applicant filing a Paragraph IV certification. The stay period and statutory barrier are maintained in place only by the continuous prosecution of the patent infringement suit and are abatable and terminable upon *the* patent holder's withdrawal, discontinuance, dismissal, or other termination of the patent infringement suit.

38. If the patent holder that filed a suit within 45-days from receipt of notification of a Paragraph IV certification, and thereby prompted the imposition of the statutory stay period, withdraws, discontinues, dismisses, or otherwise terminates the suit, the stay period immediately terminates, the FDA replaces the previously issued tentative approval of an ANDA with a final approval, and the recipient of the final approval can proceed to market immediately.

B. Defendants' Anticompetitive Conduct

1. Defendants' Original Anticompetitive Conduct Concerning TriCor Capsules

39. Defendants first marketed TriCor in the United States in December 1993 in the form of fenofibrate capsules ("TriCor Capsules") marketed under three different milligram formulations: 67 Mg, 134 Mg, and 200 Mg.[1] Defendants listed United States Patent No. 4,895,726 (the "'726 patent") in the Orange Book as claiming TriCor Capsules and thereby represented to the FDA, and potential generic manufacturers, that a claim of patent infringement could reasonably be asserted against an unlicensed manufacturer or seller of the listed drug. In 2000, generic manufacturers Impax Laboratories, Inc. ("Impax") and

[1] Fenofibrate products reduce high levels of low-density lipoprotein cholesterol ("LDL-C"), sometimes referred to as "bad cholesterol," and triglycerides by promoting the dissolution and elimination of fat particles in the blood. Fenofibrate products also increase levels of high-density lipoprotein cholesterol sometimes referred to as "good cholesterol," and reduce LDL-C in patients with primary hypercholesterolemia (high bad cholesterol) or mixed dyslipidemia (high bad cholesterol and high triglycerides). Fenofibrate products are also effective at reducing triglycerides in patients with hypertriglyceridemia (high triglycerides).

Novopharm, Ltd., a subsidiary of Teva Pharmaceuticals USA (collectively "Teva") filed ANDAs with the FDA seeking to market generic versions of TriCor Capsules. Because Defendants had listed the '726 patent in the Orange Book as claiming TriCor Capsules, Impax and Teva were required to file Paragraph IV certifications with their ANDA asserting that their formulations would not infringe the '726 patent.

40. In April of 2000, within the 45-day period provided in the Hatch Waxman Amendments, Defendants filed three lawsuits against Teva for infringement of the '726 Patent in the United States District Court for the Northern District of Illinois, thereby automatically triggering the thirty-month stay on approval of Teva's ANDA. Beginning in August of 2000, within the 45-day period provided in the Hatch Waxman Amendments, Defendants filed three lawsuits against Impax for infringement of the '726 patent in the United States District Court for the Northern District of Illinois, thereby automatically triggering the thirty-month stay on approval of Impax's ANDA.

41. Defendants, with full knowledge that neither Teva nor Impax had infringed the '726 patent, proceeded with the six baseless patent infringement actions solely to invoke the 30-month Hatch Waxman stay. This conduct had the effect of preventing a generic version of TriCor from coming to market while the sham litigation progressed and consequently of illegally extending Defendants' monopoly on TriCor and its generic equivalents. Defendants' patent litigations against Teva and Impax were objectively baseless and were brought solely for the anticompetitive purpose of delaying generic competition.

42. On March 19, 2002, Teva was awarded summary judgment of non-infringement in all three patent infringement actions brought against it by Defendants. Defendants appealed the district court's summary judgment ruling, but the Federal Circuit affirmed on March 20, 2003, holding that Teva's fenofibrate formulation did not infringe the

'726 patent. On March 26, 2003, Impax was also awarded summary judgment of non-infringement in all three patent infringement actions brought against it by Defendants.

43. After successfully defending against Defendants' sham patent litigations, Teva informed the FDA that pursuant to section 505(j)(5)(B) of the Hatch Waxman Amendments, the thirty-month stay on approval should be lifted because Teva received a final court decision in its favor. On April 9, 2002, the FDA granted final approval to Teva to market the 134 Mg and 200 Mg versions of its fenofibrate capsules, but could not grant final approval to Teva's 67 Mg version because Defendants had appealed the summary judgment decision. Under the FDA guidelines at the time the 67 Mg ANDA was filed, the FDA defined a "Court decision" under section 505(j)(5)(B) to mean a decision of a court "from which no appeal can be or has been taken." Approval of Teva's 67 Mg version was therefore further delayed until after the Federal Circuit affirmed the district court's grant of summary judgment to Teva.

44. On February 20, 2002, FDA granted tentative approval to Impax of its ANDA to market the 67 Mg, 134 Mg, and 200 Mg fenofibrate capsules. The letter from the FDA granting tentative approval indicates that the FDA determined that Impax's fenofibrate capsules were bioequivalent to Defendants' TriCor Capsules and that Impax had satisfied all the other regulatory requirements for sale of its fenofibrate capsules in the United States. Notwithstanding these determinations, however, the FDA was prevented from granting final approval to Impax because of Defendants' sham patent litigations and the thirty-month Hatch Waxman stay. On October 27, 2003, after Impax won summary judgment on Defendants' sham patent infringement claims, the FDA granted final approval to Impax to market its fenofibrate capsules.

45. By filing sham patent litigations against Impax and Teva, Defendants wrongfully delayed FDA approval of a generic version of TriCor. Defendants were not satisfied merely to delay such competition, however, and instead took affirmative steps to destroy such competition entirely. Defendants accomplished this goal by using the wrongful delay created by their sham litigation to aggressively convert patients from TriCor Capsules to 54Mg and 160 Mg TriCor tablets ("TriCor Tablets"). Once this market switch was complete, Defendants destroyed the market for TriCor Capsules, by removing the fenofibrate capsule code from the National Drug Data File ("NDDF"), and removing (or "obsoleting") TriCor Capsules from the market. By removing the capsule code from the NDDF, Defendants rendered the TriCor capsule code, to which the generic capsules would have been compared, obsolete. Because the generic capsules of Impax and Teva could not be referenced to a TriCor capsule code, and because Defendants removed TriCor capsules from the market and ceased detailing the capsule formulation, there was no longer a brand reference drug for the fenofibrate capsules of Impax and Teva.

46. Defendants delayed FDA approval of a generic fenofibrate capsule through sham litigation, and used this delay to switch the market out from under the generic manufacturers. As a result, even after successfully defending the sham infringement suits, the generic manufacturers were prevented from entering the market. Defendants' wrongful conduct indefinitely delayed the launch of generic TriCor, even after the FDA determined that the generic product satisfied all the regulatory requirements of sale in the United States. Defendants' conduct also had the purpose and effect of ensuring that, once a generic company was able to launch a competitive generic TriCor, the market that otherwise would have existed (and would have continued to exist) for the generic product no longer existed, so

the generic product was not able to compete with TriCor. As a result, Defendants' were able to maintain and prolong their monopoly position.

47. It was not necessary for Defendants to have removed the capsule code from the NDDF merely because Defendants chose to cease marketing the capsule formulation. Had Defendants maintained the capsule code in the NDDF, there would still have been a reference for which generic capsules could have been substituted, and thus there would have been a market for generic fenofibrate capsules. However, without Defendants' branded TriCor capsule code as a reference, and without the persistence of TriCor Capsules in the marketplace, there was no longer a market for generic fenofibrate capsule products. Generics were effectively blocked from the market.

2. Defendants' Anticompetitive Conduct Concerning TriCor Tablets

48. After Defendants' employed their "delay, switch and destroy" strategy with TriCor Capsules, generic manufactures seeking to market generic TriCor had no choice but to file ANDAs seeking to manufacture fenofibrate tablets in 54Mg and 160 Mg tablets. In 2003, both Impax and Teva again sought to enter makrket in the United States by filing ANDAs for 54Mg and 160 Mg fenofibrate tablets. Incredibly, Defendants employed the same strategy of causing delay by filing patent litigations against generic manufacturers while working to switch the market from 54Mg and 160 Mg TriCor Tablets to a new version of TriCor tablets while destroying the market for the 54Mg and 160 Mg TriCor Tablets.

49. Since September 2001, when Defendants executed their original "delay, switch, and destroy" strategy, Defendants' TriCor Tablets have accounted for over 95% of all sales of fenofibrate products, and 100% of all fenofibrate tablet sales, in the United States. For the twelve months ending September 2004, these products had sales in the United States in excess of $750 million.

50. Defendants originally listed the '726 patent as well as U.S. Patent Nos. 6,074,670 ("the '670 patent) and 6,277,405 ("the '405 patent") in the Orange Book as claiming TriCor Tablets and thereby represented to the FDA, and potential generic manufacturers, that a claim of patent infringement could reasonably be asserted against an unlicensed manufacturer or seller of the listed drug. In 2003, Teva and Impax filed ANDAs with the FDA seeking to market generic versions of TriCor Tablets. Because Defendants had listed the '726 patent, '670 patent, and '405 patent in the Orange Book as claiming TriCor Tablets, Impax and Teva were again required to file Paragraph IV certifications with their ANDAs asserting that their formulations would not infringe these patents.

51. Within the 45-day period provided in the Hatch Waxman Amendments, Defendants filed a patent infringement action in the United States District Court for the District of Delaware against Impax for infringement of the '670 patent and the '405 patent. Within the 45-day period provided in the Hatch Waxman Amendments, Defendants filed a patent infringement action in the United States District Court for the District of Delaware against Teva for infringement of the '670 patent and the '405 patent.

52. Defendants' patent infringement actions against Impax and Teva concerning the '670 and '405 patents triggered an automatic 30-month stay under HatchWaxman that prevented the FDA from granting final approval for so long as the statutory stay remains in effect. On or about July 23, 2003, Defendants listed another Patent, U.S. Patent No. 6,589,552 ("the '552 patent") in the Orange Book as claiming TriCor Tablets. Pursuant to the Hatch Waxman Amendments, Teva and Impax were required to amend their tablet ANDAs to make an additional Paragraph IV certification that their fenofibrate tablet formulations did not infringe the '552 patent.

53. In response to Impax and Teva's Paragraph IV certifications to the '552 Patent, Defendants filed two more patent infringement actions in September of 2003. In their complaints, Defendants contended that Impax's and Teva's Tablet ANDAs infringed the '552 Patent.

54. Defendants' patent infringement actions against Impax and Teva concerning the '552 patent triggered an additional 30-month automatic stay period under Hatch Waxman. This successive 30-month stay commenced and continued in effect more than nine months after the first 30-month stay that went into effect with the filing of the first patent infringement actions concerning the '670 and '405 patents.

55. On or about December 12, 2003, Defendants listed yet another patent, U.S. Patent No. 6,652,881 ("the '881 patent'), in the Orange Book as claiming TriCor Tablets. Pursuant to the Hatch Waxman Amendments, Teva and Impax were again required to amend their tablet ANDAs to make an additional Paragraph IV certification that their fenofibrate tablet formulations did not infringe the '881 patent.

56. In response to Impax and Teva's Paragraph IV certifications to the '881 Patent, Defendants filed two more patent infringement actions in January of 2004. In their complaints, Defendants contend that Impax's and Teva's Tablet ANDAs infringed the '881 Patent.

57. On March 5, 2004, the FDA granted tentative approval to Impax's Tablet ANDA. By granting tentative approval, the FDA indicated that Impax's fenofibrate tablets are bioequivalent to TriCor Tablets of the same dosage strengths. On April 22, 2005, the FDA granted tentative approval to Teva's Tablet ANDA. By granting tentative approval, the FDA indicated that Teva's fenofibrate tablets are bioequivalent to TriCor Tablets of the same dosage strengths.

58. In the case of TriCor Tablets, Defendants again used the delay engendered by their sham litigation to convert the market and further thwart generic competition and maintain their monopoly. This time, again facing an imminent threat of generic competition, Defendants switched the market from the 54 mg and 160 mg tablet formulations to new tablet formulations that involve the same medicine and are indicated for essentially the same uses as the old formulation tablets.

59. Shortly after Defendants affected the market switch from capsules to tablets, Defendants filed an ANDA for a new fenofibrate tablet that will be marketed in 48 mg and 145 mg tablet dosage forms, and will replace Defendants' current 54 mg and 160 mg tablet dosage forms. Defendants have already begun marketing their new TriCor tablets, and they have began aggressively switching patients to the new tablets. Based on the previous experience of the switch from the capsule to tablet, it is likely that Defendants will remove the 54 mg and 160 mg TriCor tablets from the NDDF in the near future.

60. Defendants' conduct is intended to ensure, and likely will ensure, that no new prescriptions are written for the 54 mg and 160 mg fenofibrate tablet formulations, and that current prescriptions for the 54 mg and 160 mg fenofibrate tablet formulations are converted to the replacement formulations. In the future, this will mean that a pharmacist will not be presented with a prescription that would allow for substitution with a generic version of the 54 mg and 160 mg tablet formulations, should one become available.

3. Defendants' Have Engaged In An Anticompetitive Pattern And Practice Of Conduct To Thwart Generic Entry

61. Defendants' have engaged in an anticompetitive pattern and practice of conduct to thwart generic entry. The components of this scheme include the following:

a. Defendants bring a particular formulation of TriCor to market in the United States;

b. When competitors develop and seek to sell lower-cost bioequivalent generic products in competition with Defendants' TriCor, Defendants engage in sham patent infringement litigation which has the purpose and effect of delaying the launch of competitive generic products until after they are able to launch a new formulation of TriCor;

c. During the period when Defendants' delay tactics block competitive generic drug rivals from the market, Defendants exploit their monopoly to charge supracompetitive prices for TriCor. Those prices are far higher than the prices generic drug rivals would charge if they were able to sell their bioequivalent products. However, because Defendants have excluded competitive products from the market, they can maintain supracompetitive prices without losing sales;

d. Once market entry by competitive generic drug products appears imminent, Defendants begin selling a new formulation of TriCor. The new formulation is the same medicine, used for essentially the same indications, as the existing formulation. In addition, Defendants take affirmative steps to convert customers from the existing formulation to the new formulation before the competitive generic products are available for sale;

e. Not all patients or doctors would switch from the old formulation to the new formulation, despite Defendants efforts to convert them. Therefore, Defendants take additional affirmative steps, which are separate from simply launching the new formulation product, to destroy any existing market for the old formulation before the competitive generic products

are available for sale, such as removing the TriCor product code from the NDDF, rendering such codes, to which generic fenofibrate would be been compared, obsolete.

f. As a result, once a generic drug company is able to start selling its product - which is bioequivalent to the old TriCor formulation product and therefore could be substituted by a pharmacist for the old product - the market for that product has been switched to the new product. Moreover, because the generic product is a different dosage and formulation from the new TriCor, pharmacists and others cannot legally substitute the generic product for the new TriCor, even though the products are indicated for the same uses. The product switch effectively destroys generic competition which otherwise would have existed.

62. By engaging in this pattern and practice, and repeating it, Defendants can postpone generic competition in the sale of TriCor indefinitely. By so doing, Defendants improperly maintain and extend their TriCor monopoly, harming direct purchasers and depriving consumers of access to lower-cost bioequivalent medicines. Defendants conduct constitutes an improper overall scheme to monopolize the sale of TriCor and its generic equivalents in the United States in violation of the federal antitrust laws and other laws.

EFFECTS ON COMPETITION

63. Defendants exclusionary conduct has delayed generic competition and unlawfully enabled Defendants to sell TriCor without being subject to generic competition. But for Defendants' illegal conduct, generic competitors would have begun marketing generic versions of TriCor products much sooner.

64. If generic competitors had not been unlawfully prevented from earlier entering the market and competing with Defendants, direct purchasers, such as Plaintiffs, would have been free to substitute a lower-priced generic for the higher-priced brand name drug and consequently would have paid substantially less for TriCor and its generic equivalents.

65. By preventing generic competitors from entering the market, Defendants injured Plaintiffs by causing them to pay more for TriCor than they otherwise would have paid. Defendants' unlawful conduct deprived Plaintiffs of the benefits of competition that the antitrust laws were designed to preserve.

66. To the extent that defining relevant product markets is necessary in this case, the relevant product market is TriCor and its generic equivalents. The relevant geographic market is the United States. Defendants currently hold a monopoly share in the relevant product and geographic markets. Accordingly, Plaintiffs and members of the Class continue to pay higher prices for TriCor and its generic equivalents than they would otherwise have paid, as a result of Defendants' unlawful extension of its patent monopoly through the conduct alleged herein.

VIOLATIONS OF SECTION 2 OF THE SHERMAN ANTITRUST ACT

67. Plaintiffs incorporate by reference the preceding allegations.

68. Defendants knowingly and willfully engaged in a course of conduct designed to extend unlawfully their monopoly power. This course of conduct included improperly filing and prosecuting sham patent infringement actions against companies seeking to market competing generic versions of TriCor and improperly switching and destroying markets for TriCor and its generic equivalents to prevent generic competition. Defendants' conduct was designed to delay the introduction of a generic version of TriCor into the market and was in violation of Section 2 of the Sherman Act.

69. Defendants intentionally and wrongfully maintained their monopoly power with respect to TriCor in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2. As a result of this unlawful maintenance of monopoly power, Plaintiffs and members of the Class paid artificially inflated prices for TriCor and its generic equivalents.

70. Plaintiffs and members of the Class have been injured in their business or property by reason of Defendants' antitrust violations. Their injury consists of having paid and continuing to pay higher prices for TriCor than they would have paid in the absence of those violations. Such injury, namely overcharges, is of the type antitrust laws were designed to prevent and flows from that which makes Defendants' conduct unlawful.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully pray for the following:

A. Judgment in their favor and against Defendants for damages representing the overcharge damages sustained by Plaintiffs and the other members of the Class defined herein, trebled;

B. Pre- and post-judgment interest;

C. Costs of suit, including reasonable attorneys' fees;

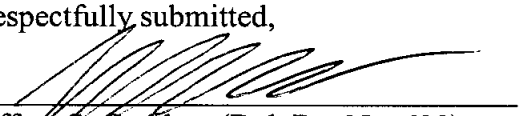
D. Such other and further relief as the Court deems just and proper.

JURY TRIAL DEMANDED

Pursuant to Fed. R. Civ. P. 38(b), Plaintiffs demand a trial by jury of all of the claims asserted in this Complaint so triable.

Dated: June 3, 2005

Respectfully submitted,



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